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14. ABSTRACT This study aims to address the dearth in basic science in suicidology by looking at components of two new psychological models that endeavor to identify suicide-specific individual differences factors and patterns of thinking; the Integrated Motivational Volitional Model (IMV; O'Connor 2011) and the Interpersonal Psychological Theory of Suicide (IPT; Joiner, 2005). The project is divided into 6 separate studies (experimental, prospective, clinical) that aim to advance our understanding of the basic psychological processes associated with suicidal ideation and behavior. Study 1; the Scottish Wellbeing Study is a large scale general population based prospective study of young people across Scotland. Study 2 uses a clinical population of patients recently admitted to hospital for self-harm with follow-up. Studies 3 and 4 are longitudinal studies that incorporate an experimental component designed to compare changes in pain sensitivity before and after a social stress or defeat manipulation. Studies 5 and 6 investigate the relationship between heightened stress reactivity and suicidality in both a laboratory and real-life setting. Baseline recruitment is complete for studies 1, 2 and 5 and is ongoing for studies 3, 4, and 6.					
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## **Introduction: The importance of basic science**

There has been a growing consensus that we need to move beyond psychiatric diagnoses to better understand suicide; suicide is the result of a complex interplay of psychological, social and biological factors. A more sophisticated attempt to model the antecedents of suicidal behavior is needed to understand the basic mechanisms underpinning suicide. Military personnel encounter frequent physiological/psychological stressors, therefore identifying suicide risk and resilience factors in military personnel is vital; so those who may be vulnerable can be targeted for early intervention and preventative treatment (MacDermott, 2010). Whilst the present research is not being conducted in a military sample, the fundamental psychological processes that underpin suicide risk are likely to be universal. New psychological models have been developed to aid the identification of suicide-specific individual difference factors and patterns of thinking. This program of research addresses the dearth of basic science research in suicidality by looking at components of two new psychological models; the Integrated Motivational-Volitional Model (IMV; O'Connor, 2011) and the Interpersonal Psychological Theory of Suicide (IPT; Joiner, 2005). Both of these models attempt to explain why some people experience suicidal ideation but do not go on to engage in suicidal behavior (ideators-only) whereas others experience suicidal ideation and translate this ideation into suicidal behavior (attempters).

STEPPS includes 6 separate studies, employing a combination of experimental, prospective and clinical study designs (see below). Each study uniquely investigates different aspects of the models. Importantly, no previous research has looked specifically at this combination of psychological measures across different populations (i.e., general populations, clinical populations) and the findings will inform the development of interventions. A brief overview of the studies is provided below:

- Study 1: Scottish Wellbeing Study – large scale general population-based study of young people across Scotland (observational longitudinal)
- Study 2: Psychological Factors in Self-harm Study – clinical population study of patients recently admitted to hospital for self-harm (observational longitudinal)
- Studies 3/4: The Relationship between Social Stress/Defeat & Pain Sensitivity – experimental studies comparing changes in pain sensitivity before/after social stress/defeat manipulation (experimental and longitudinal)
- Studies 5/6: The Relationship between Stress Reactivity and Suicide Risk – aims to investigate relationship between heightened stress reactivity to stress exposure and suicidality (experimental).

## **Body**

The original start date for the STEPPS project was April 1<sup>st</sup> 2012. However due to delays finalizing the contract, the start date was moved to July 2012. In July 2013 the STEPPS team transferred from University of Stirling to University of Glasgow. Prior to the move procedures were put in place to reduce the potential impact on the studies that were actively recruiting. As a result only study 4 experienced any disruptions to recruitment. Following the in-progress review meeting in May 2013 the project we have incorporated further follow-ups for Studies 1, 3 and 4. The study timeline and milestones have been adjusted accordingly and we are currently on-schedule.

### Study1: Scottish Wellbeing Study

#### **Overview**

This study is observational and longitudinal (baseline, 12 and 24 month follow-up). A quota sampling methodology with quotas based on age (three quota groups), sex and working status was used at baseline. The baseline interviews were carried out face-to-face, using Computer Assisted Personal Interviewing (CAPI), including a Computer Assisted Self Interviewing (CASI) module (for completion of sensitive questions including suicidal history and well-being).

At the 12 (time 2) and 24 (time 3) month follow-up participants are asked to complete a shorter packet of measures. Participants choose their method of completion at follow-up (phone, email, post). Baseline data collection was completed in December 2014 (3508 participants). Time 2 follow ups are ongoing.

#### **Sampling Methodology**

To fulfill the study aim, data was collected through face-to-face interview at time 1 and will be collected through a choice of interview delivery at time 2 and time 3 (postal, telephone, email). We used a quota design. Given the survey is targeting such a narrow age range – a group often ‘hard to reach’ – a quota design offers a much more practical approach to carrying out the survey than traditional pre-selected sampling, enabling us to complete fieldwork more quickly and at a lower cost. Indeed, the costs of carrying out the survey using a random design would have been prohibitive. Our sampling design for this survey used a rigorous approach to quota sampling: we strictly defined the random selection of the sampling points using census datazones, and at each point we set target quotas which were representative of the population of young adults across Scotland (aged 18 to 34 years).

#### **Study measures**

Participants completed the following outcome measures:

Suicidality History. items from the British Psychiatric Morbidity Survey (Nicholson, Jenkins & Meltzer, 2009) and the Child and Adolescent Self-harm in Europe Survey (Madge et al., 2008); recent Suicidal Ideation (Beck Scale for Suicidal Ideation, BSSI; Beck & Steer, 1993); suicidal imagery; recent Depression (The Beck Depression Inventory-II, BDI-II; Beck et al., 1996); recent Stress (perceived Stress Scale-Brief, PSS-Brief; Cohen, Kamarck, & Mermelstein, 1983); The Warwick-Edinburgh Mental Well-being Scale (WEMWBS; Tennent et al., 2007).

Additionally, they completed these predictor measures:

Lifestyle factors: exercise (Godin Lesiure-Time Exercise Questionnaire; Godin, 2011), smoking (1 question), alcohol use (3 questions taken from NHS Choices self-assessment of alcohol and CAGE assessment of alcohol use [Ewing, 1984]) and dietary intake (Eating Habits Questionnaire; Roe et al., 1994). We will ask two general questions about perceived health (overall and mental health).

Defeat (Defeat Scale, Gilbert & Allan, 1998); Entrapment (Entrapment Scale, Gilbert & Allan, 1998); Acquired Capability for Suicide (Acquired Capability for Suicide Scale, ACSS; Bender et al., 2007); Interpersonal Needs Questionnaire (INQ; Van Orden, 2009); Social support (ENRICH Social Support Instrument, ESSI; Vaglio et al., 2004); Impulsivity (Barratt Impulsiveness Scale, Version 11, BIS-11; Patton et al., 1995); Goal Reengagement and Disengagement (goal adjustment scale, GAS; Wrosch et al., 2003); Social perfectionism (Socially Prescribed Perfectionism subscale, MPS-Social of the Multidimensional Perfectionism Scale, MPS; Hewitt & Flett, 1991); Optimism (Life Orientation Test, LOT-R; Scheier, Carver & Bridges, 1994); Resilience (Brief Resilience Scale, Campbell-Sills & Stein, 2007); exposure to self-destructive behaviors and death will also be assessed.

The majority of outcome measures are being repeated at the follow-up time periods.

### **Study Population and Sample Size**

We aimed to recruit 3500 participants, both male and female, to the study to yield approximately 150-200 individuals with a suicide attempt history. This assumed a 5.6% prevalence of a lifetime suicide attempt (with 95% confidence), consistent with that reported in the Adult Psychiatric Morbidity survey conducted in England (Nicholson, Jenkins, & Meltzer, 2009). We believed a sub-sample of 150-200 'suicide attempt cases' would be sufficient and required to afford meaningful univariate and multivariate analyses. We also anticipated that a sample of 3500 would yield at least 15% of respondents who had thought about ending their lives at some stage (Nicholson et al., 2009) and as 1 in 4 people are thought to experience mental health problems, the sample would include sufficient individuals who are currently experiencing depressive

symptoms. We also aimed to investigate wellbeing more generally, including stress, optimism and the positive aspects of health. Consequently, we can reliably compare those with a history of ideation versus suicide attempt versus controls. In the analyses, we will also use a continuous measure of suicidal ideation as an outcome measure.

Inclusion criteria for this study was 18-34 year olds of both genders, and all socio-economic statuses (e.g. working full time, in full time education, unemployed/not working full time), living in households in Scotland. To be included in the study people must have been able to give informed consent.

Participants will be contacted by members of the research team for follow-up 12 and 24 months later. They will be offered a choice of method to complete the shorter follow-up (phone, email, post).

## **Update**

Time 2 follow-ups are underway. So far 65% of participants have completed the follow up. As anticipated the online questionnaire has been the most popular means for completing the follow-up. Those without email addresses have been posted a questionnaire booklet with a freepost envelope provided. Participants who do not respond to these methods of contact are then be contacted by phone. When contact with a participant has been attempted by all means unsuccessfully the secondary contact is approached by post/email/phone to help with contacting the participant. Due to the scale of the study follow-ups have been proving more challenging than anticipated, and to combat this we have devoted additional support to help with reminder phone calls. In addition we now enter participants into a prize draw to win an iPad mini for completing the follow-up. For participants who have not provided an email address we have designed personalized postcards to remind them about the follow up and to alert them to the inclusion of the prize draw.

For participants who have completed the follow-up we have sent them a postcard informing them of the prize draw. This allows us to confirm contact details and remind participants that we will be contacting them later in the year for their final follow-up. For some participants there has been a delay in collecting follow-up data and we will adjust the time 3 follow-ups allow at least 6 months between our last contact with them.

## Study 2: The Role of Psychological Factors in Self-harm

### **Overview**

This study is a clinical population study of patients recently admitted to hospital following self-harm and participant recruitment is ongoing.

This is an observational longitudinal study that aims to recruit a minimum of 500 adult (age 18+) patients from two hospitals in Central Scotland. We have employed the National Institute for Clinical and Health Excellence (NICE) guideline definition of self-harm: “intentional self-poisoning or injury, irrespective of the apparent purpose of the act”. Self-harm includes poisoning, asphyxiation, cutting, burning and other self-inflicted injuries” (NICE, 2004, 2011). However, 90% of the participants are likely to present following overdose (O’Connor, O’Carroll, Ryan and Smyth, 2012).

Patients admitted to hospital following an episode of self-harm are screened for eligibility to participate by a member of the clinical care team. Patients admitted with self-harm are required to stay in hospital for observation overnight, and will be assessed as part of their routine care the following morning. At each site, initial assessment is by a Consultant Psychiatrist, a Specialist Registrar Psychiatrist or another member of the clinical team. Following assessment, a member of the clinical care team alerts the researcher to patients who are eligible to take part. Patients are approached by a trained researcher to seek consent to participate in an interview which takes 45-60 minutes. To minimize the potential cognitive load, for all of the measures, participants have the option of providing their responses orally (the different question response options are provided on response cards).

Participants are also asked for contact details to be contacted 6 months later for a briefer follow-up. They will be offered a choice of method to complete the follow-up (phone, email or post). Participant medical records are also consulted to determine whether a participant has been admitted to hospital since time 1.

### **Study measures**

Participants are asked to complete measures of:

recent Suicidal Ideation (Beck Scale for Suicidal Ideation, BSSI; Beck & Steer, 1993); recent Depression (BDI-II; Beck et al., 1996); Defeat (Defeat Scale, Gilbert & Allan, 1998); Entrapment (Entrapment Scale, Gilbert & Allan, 1998); Acquired Capability for Suicide (ACSS; Bender et al., 2007); Interpersonal Needs Questionnaire (INQ; Van Orden, 2009); Social support (ESSI; Vaglio et al., 2004); Impulsivity (BIS-11; Patton et al., 1995); Goal Reengagement and Disengagement (GAS; Wrosch et al., 2003); Social perfectionism (MPS-Social; Hewitt & Flett, 1991).



At follow-up participants are asked to complete measures of recent suicidal ideation, depression, recent Stress (PSS-Brief; Cohen, et al, 1983) and hopelessness (The Beck Hopelessness Scale, BHS; Beck et al., 1974).

### **Study population and sample size**

500 self-harm adult patients (18+ years) have been recruited from both sites. Given that a history of suicidal behavior is the best predictor of completed suicide, we aim to conduct sub-sample analyses for the repetitive and non-repetitive self-harmers separately.

The socio-demographics of all patients admitted to both sites during the study's recruitment period is recorded. No names, addresses or identifiable information are collected on these patients. By recording the socio-demographics we will be able to determine how representative our sample is of the target population. We are confident that the sample, which we will recruit from the two hospitals, will be broadly representative of the acute self-harm admissions and no particular sub-groups will be over/under-represented.

### **Update**

Data collection for this study commenced in March/April 2013 and is now complete: All 500 participants have been recruited and have completed time 1 interviews. Recruitment went well and psychiatric staff have been supportive in alerting researchers to potential participants.

It has been challenging to contact participants at time 2 for follow up. This can be due, for example, to incorrect contact details or if the participant has moved house since time 1. In an attempt to minimize the number of participants lost to follow-up, we have been collecting as much information as possible e.g. postal address and email or phone number. In order to increase these numbers, we have tailored letters to participants so that they are as accessible as possible. We have also created a booklet to post to participants which gives clear and easy instructions on how to complete the questionnaires. Furthermore, we have created an online survey containing the questionnaires which is also easy to use, and which some participants prefer. A number of participants have provided their telephone number at time 1 and for some of these participants the follow up was conducted by telephone, which has been straightforward. Researchers have also contacted participants in the evening, so as to reach participants who may be busy during the day. By giving participants multiple possible means of completing this follow up, we hope to maximize numbers at time 2. However, as we have participants' permission to access their medical records we will be able to determine whether participants

have been hospitalized with a suicide attempt/died by suicide during the follow-up period. This data collection is expected to continue until the end of the study.

### Study 3: The Relationship Between Social Stress and Pain Sensitivity

#### **Overview**

This is a longitudinal study which incorporates an experimental component. Participants will attend an appointment at the university's lab and take part in the experimental part designed to compare changes in pain sensitivity before and after a social stressor manipulation with the aim of determining the relations between components of the IPT/IMV & pain sensitivity and the impact that social stress has on pain sensitivity.

During the appointment they will complete a series of questionnaires (Part 1) followed by the experimental phase of the study (Part 2). Participants will be asked for their consent to be contacted 1 month and 6 months after their lab visit.

#### **Part 1: Study Measures**

Participants will complete measures of:

Suicidality History, recent Suicidal Ideation (BSSI; Beck & Steer, 1993); recent Depression (BDI-II; Beck et al., 1996); recent Stress (PSS-Brief; Cohen, et al, 1983).

Defeat (Defeat Scale, Gilbert & Allan, 1998); Entrapment (Entrapment Scale, Gilbert & Allan, 1998); Acquired Capability for Suicide (ACSS; Bender et al., 2007); Interpersonal Needs Questionnaire (INQ; Van Orden, 2009); Social perfectionism (MPS-Social; Hewitt & Flett, 1991).

#### **Interview**

MINI (Mini International Neuropsychiatric Interview). The MINI is a brief, structured interview assessing various categories of current Axis I disorders. Following the MINI will be a brief interview asking participants to indicate history of various categories of disorders, treatments, as well as psychiatric hospitalizations.

Self-Injurious Thoughts and Behaviors Interview – Short Version. Participants will complete a short version of the Self-Injurious Thoughts and Behaviors Interview (SITBI; Nock, Holmberg, Photos, & Michel, 2007). The SITBI allows a thorough assessment of history of self-injurious thoughts and behaviors. It is comprised of five modules corresponding to the five types of self-injurious thoughts and behaviors (SITB): non-suicidal self-injury, suicide plan, suicide gesture, suicide ideation, and suicide attempt. In each module, if the initial screening question is endorsed, then the corresponding follow-up questions are included in the interview. The follow-up questions include frequency of the particular SITB, severity and duration of thoughts, functions from Nock & Prinstein's (2004) model, methods of certain SITB (e.g., NSSI), and future likelihood of engaging in the SITB.

## **Part 2: Experimental Phase**

Mood Checks: Participants will be asked to rate their mood on three 100mm Visual Analogue Scales (VAS) at four different points during the study. “At this moment I feel...” and the mood (defeated, happy, sad) will be anchored on a scale of not at all to extremely (consistent Johnson et al. 2008).

### Physical Pain Sensitivity

**Algometer Task:** this is a handheld pressure gauge fitted with a 1-cm diameter rubber tip. Consistent with Gratz et al. (2011), the gauge is calibrated in Newtons with a range to 20 kg × 200 g. This instrument will be applied perpendicular to the middle of participants' non-dominant palm at a gradually increasing rate of pressure by the researcher. Participants will be asked to indicate when they first perceive pain due to the pressure increase, and when the pain is too uncomfortable to continue. Latencies in seconds will be used as indices of pain threshold and pain tolerance, respectively. The reliability of the pressure algometer has been established previously (Gratz et al, 2011).

**Cold Pressor Task (CPT):** a cold pressor unit will be filled with water at a temperature of 37.4°F ± 1°F (3°C). Participants will be asked to immerse their dominant hand in the water, keeping it still. Participants will (a) be asked to report when the sensation starts to become uncomfortable and (b) be instructed to keep their hand submerged in the water for as long as they can. They will be informed that they can remove it at any time if the pain becomes too uncomfortable. Both of these measures are widely used with participants and only yield mild levels of discomfort.

### **Social Stressor Manipulation**

The social stressor manipulation will be based on the interpersonal situation manipulation devised by Lang and colleagues and used recently by Gratz et al. (2011). We will employ a modified version of this protocol, wherein semi-structured interviews will be conducted to elicit a recent interpersonal encounter/situation with an individual whom the participant has an ongoing relationship (Gratz et al., 2011). There will be two conditions. First, in the experimental condition, participants will be asked to think of a recent time when they became ‘very angry or upset’. Second, in the control condition, participants will be asked to think of two situations about which they ‘felt mostly neutral, and had neither unpleasant nor pleasant feelings’. They will be asked to describe the interactions in detail including how they felt at the time.’

At follow up participants will be asked to complete measures of recent suicidal ideation and self-injurious behaviors.

## Study population and sample size

A total of 135 healthy adults (over age 18 years) will be recruited to the study. This is consistent with similar research conducted by this research group previously (e.g. O'Connor, Smyth, Ryan & Williams, 2012) a sample size of 45 per group is adequate to detect a medium effect setting alpha at .05 and power at .80.

We aim to be as inclusive as possible in our studies and try to only exclude people who are unable to give fully informed consent. However, due to the use of the algometer as a pain tolerance measure those with medical conditions including; heart or circulation problems, blood pressure problems, epilepsy, Reynaud's Syndrome, chronic pain conditions and recent injury of a serious nature will be excluded. Due to the use of the cold pressor test (CPT), people with diabetes will also be excluded. Participants also need to have been free of analgesics for at least 8 hours prior to the study.

## Update

We are about halfway through recruitment to this study with 72 participants recruited so far. The table below shows a breakdown of recruitment to the participant groups.

		1 month Follow-up				6 month Follow-up			
Group	Participants	Completed	Due now	Due future	Missed	Completed	Due now	Due future	Missed
Controls	23	22	1	0	0	2	1	20	0
Ideators	28	24	1	3	0	8	0	20	0
Attempters (Lifetime)	21	20	0	1	0	4	1	16	0

We have used our experiences from study 4 to review and inform procedures for this study. For instance, we have found that getting participants to administer pressure at a constant rate via the algometer challenging. To address this concern the Research Assistants will be trained to administer pressure via the algometer at a constant rate of pressure of .5 kg/second as per Gratz et al., (2011) study. Additionally the algometer is now applied to the participant's palm rather than finger as during piloting it was found by both Research Assistants to be very challenging to keep the tip of the algometer from sliding off the area.

As expected one of the challenges to this study has been recruiting the target number of people with a history of suicidal ideation or behavior. We have experienced this in other studies, and use a wide range of advertising strategies to overcome this.

During the pilot phase of the study (May 2014) both algometers stopped working and had to be sent away for repair which delayed recruitment to the study.

**Follow up**

We employ various methods to follow up participants (including evening telephone calls and the option of completing it online) which has ensured that we maintain a high rate of follow up with no follow-ups missed so far.

## Study 4: The Relationship Between Defeat and Pain Sensitivity

### **Overview**

Study 4 has a similar design to Study 3 as it is also longitudinal with an experimental component. Participants attend an appointment at the university's lab and take part in the experimental part designed to compare changes in pain sensitivity before and after a defeat manipulation with the aim of determining the relations between components of the IPT/IMV & pain sensitivity and the impact that manipulating defeat has on pain sensitivity.

During their appointment they complete a series of questionnaires (Part 1) followed by the experimental phase of the study (Part 2). Participants are asked for their consent to be contacted one month and six months after their lab visit.

### **Part 1: Study Measures**

Participants complete measures of:

Suicidality History, recent Suicidal Ideation (BSSI; Beck & Steer, 1993); recent Depression (BDI-II; Beck et al., 1996); recent Stress (PSS-Brief; Cohen, Kamarck, & Mermelstein, 1983). Defeat (Defeat Scale, Gilbert & Allan, 1998); Entrapment (Entrapment Scale, Gilbert & Allan, 1998); Acquired Capability for Suicide (ACSS; Bender et al., 2007); Interpersonal Needs Questionnaire (INQ; Van Orden, 2009); Social perfectionism (MPS-Social; Hewitt & Flett, 1991).

### **Interview**

Following completion of the measures participants go through a brief interview to indicate history of various categories of disorders, treatments, as well as psychiatric hospitalizations.

Self-Injurious Thoughts and Behaviors Interview – Short Version. Participants complete a short version of the Self-Injurious Thoughts and Behaviors Interview (SITBI; Nock, Holmberg, Photos, & Michel, 2007). See study 3 for further details on the interview.

### **Part 2: Experimental Phase**

Mood Checks: Participants are asked to rate their mood on three 100mm Visual Analogue Scales (VAS) at four different points during the study. "At this moment I feel..." and the mood (defeated, happy, sad) are anchored on a scale of not at all to extremely (consistent Johnson et al. 2008).

### Physical Pain Sensitivity

The Algometer Task and Cold Pressor Task are employed to assess Pain Sensitivity. Full details of these tasks are given in Study 3.

### **Defeat/ No defeat manipulation**

Defeat/no defeat is induced following procedures adapted from Pegg, Deakin, Anderson, & Elliott (2006) by Johnson et al. (2008). Both manipulations comprise two 30 trial computerized tasks (an anagrams task and a 'before and after task') which run on e-prime software.

In the anagrams task, participants are required to form new words using all the letters in target words (e.g., 'melon' could be created from 'lemon'). In the 'before and after' task, participants are instructed to select a word from a list which would fit between two target words to make a new word of each (e.g., if presented with 'data\_\_\_\_ball', selecting the word 'base' would make a new word of each target word (database and baseball). There are two versions of each task; one impossible and one achievable version. Participants in the defeat (experimental) condition receive the impossible version of the tasks and those in the no defeat (control) condition receive the achievable version. See protocol for full details of manipulations.

At follow up participants are asked to complete the measures of recent suicidal ideation and self-injurious behaviors.

### **Sample population and sample size**

165 adults (over age 18) will be recruited to a suicidal ideation (n=55), previous suicide attempt (n=55), and a control group (n=55). This participant number is consistent with similar research conducted by this research group previously (e.g. O'Connor, Smyth, Ryan & Williams, 2012) the sample size was deemed to be sufficient to detect a medium effect in this population. Adopting an effect size of .35 (informed by previous studies conducted by our group) and setting an alpha at .05 and power at .80 a power calculation yielded a sample size of 132 (O'Connor, Hendrix et al., 2009; Walker et al., 2011).

### **Update**

This study originally aimed to recruit 135 participants, however, to ensure that we can investigate gender differences and to ensure that we have proportionate number of men to the suicidal ideation group, we extended recruitment. Ethical approval for this amendment was obtained in January 2015.

As with Study 3, recruitment to this study was slightly delayed by equipment failure in May last year, but is back on schedule. The table below shows a breakdown of recruitment to the participant groups.



		1 month Follow-up				6 month Follow-up			
Group	Participants	Completed	Due now	Due future	Missed	Completed	Due now	Due future	Missed
Controls	45	43	0	0	2	42	0	0	3
Ideators	55	54	0	0	1	43	2	4	6
Attempters (Lifetime)	49	45	1	1	2	38	0	4	8

### Follow up

As with study 3 we employ various methods to follow up participants which has ensured that we maintain a high rate of follow up across the 2 follow ups.

### Study 5: Stress & Wellbeing Study

A total of 160 participants were recruited and completed the baseline laboratory visit. All participants were contacted for a one follow up assessment, and to date 145 participants have been contacted regarding their six month follow up. The remaining 15 participants are due to be contacted between now and June 2015. The breakdown for group allocation and follow up rates are shown in Table 1.

	n	1 month (%)	6 months (%)	TBC (%)
All Groups	160	151 (94.38)	133 (83.13)	15 (9.38)
Controls	45	44 (97.77)	40 (88.88)	4 (8.88)
Ideators	46	44 (95.65)	39 (84.78)	4 (8.70)
Attempts	40	38 (95.00)	30 (75.00)	5 (12.50)
In between groups	12	11 (91.66)	10 (83.33)	1(8.33)
Exclusions	17	14 (82.35)	14 (82.35)	1 (5.88)

Twelve participants are currently categorised as 'in between groups', because their history of suicidal behaviour is ambiguous. Each participant will be reviewed individually, taking into consideration their responses at each time point. A judgement will be made on whether they can be allocated into the ideators or attempters group, or whether an interstitial category will need to be created.

Seventeen participants have been identified who may need to be considered for exclusion. The main reason(s) for this are; (1) incomplete MAST, (2) participants' self-reported ideation was more historical than initially disclosed at the screening stage, or (3) participants were screened into the control group but reported a history of suicidal ideation or behaviour at a

later time point. Again, these cases will be reviewed and a judgement will be made to whether they need to be excluded from some, or all of the analyses.

Data entry has been completed for all available data.

#### Cortisol and Interleukin Analysis

Oral swabs and passive drool samples for all 160 participants have been analysed by Salimetrics Europe Ltd.

Cortisol. Out of a possible 1120 samples, 37 were not completed because the participant was withdrawn from the study, 11 had insufficient saliva for analysis and 1 was blood contaminated; leaving a total of 1071 viable samples for analysis.

Interleukins. Out of a possible 320 samples, a mean concentration of IL-1 $\beta$  was available for 306 samples. Reasons for missing data were as follows; insufficient saliva for analysis (n=4); blood contamination (n=2); poor sample quality (n=1); analyte concentration below the limit of sensitivity for assay (n=6) and one of the duplicate concentrations being too low to extrapolate a mean concentration value (n=1).

Out of a possible 320 samples, a mean concentration of IL-6 was only available for 183 samples. The main reason data were not available was because the analyte concentration was below the limit of sensitivity of the assay (n=118). However this data may still be viable for analysis; samples could be dichotomised into those which have a detectable level of IL-6, compared to those which did not, and this may prove informative. Further reasons for missing data were as follows; insufficient saliva for analysis (n=5); blood contamination (n=2); poor sample quality (n=1); and one of the duplicate concentrations being too low to extrapolate a mean concentration value (n=11).

#### Study 6: Daily Stressors & Wellbeing Study

Ethical approval for study six was obtained from the IRB (University of Leeds) on the 19th August 2014, and from the HRPO on the 14th September 2014.

#### *Pilot Study*

Five participants piloted the procedure for Study 6; three in December 2014 and two in January 2015. Participants also completed feedback questionnaires and, in general, they reported that the instructions they received were clear and straight forward, and they encountered minimal problems.

However, some minor issues did arise and the following changes were made after the first stage of piloting (ppts 1-3) and the second (ppts 4-5).

#### Changes made after Piloting Round 1

ISSUE: GENEActiv devices were set to start recording at 00:00 on Day 1. However, because the watch was not activated before bedtime the previous night, a wake up time was not available for the first day

SOLUTION: The GENEActiv device will now begin recording from disconnect.

ISSUE: One participant did not receive any of their nightly SMS reminders.

SOLUTION: A 'test' text message will be sent to participants whilst they are still in the lab. This will confirm that the correct number has been stored and they can receive the message without any problems, and if they do not receive the message we can try and resolve this whilst they are on site.

ISSUE: One GENEActiv device registered that it was not worn for the majority of the first four days. This may have been because the participant slackened off the watch to such an extent it registered as not being on the skin.

SOLUTION: For the 2nd round of piloting we asked participants to keep it as tight as is comfortable, and no instances of non-wear were recorded.

#### Changes made after Piloting Round 2

ISSUE: Some participants reported that it was difficult to remember when to take the additional sample to measure interleukins.

SOLUTION: Participants will be sent text messages on the two days they are required to take their additional samples.

ISSUE: Discrepancies were found between participants' self-reported wake up and the 'out-of-bed' time reported on the GENEActiv summary sheet, which are calculated using macros. However, after investigating the full data array and speaking with a GENEActiv advisor, it was discovered that the 'rise' time reports when the participant is believed to be out of bed and moving around, rather than when they awake.

SOLUTION: In the full data array there is a distinction made between BED and SLEEP, and the data provided in the SLEEP column was found to be fairly consistent with the self-reported wake times. Therefore the wake time will need to be determined by a researcher and entered manually into the macros report. After the first three participants, we also included space in the daily record book for participants to write down their morning routine

whilst taking the samples, to gather more information about whether they remain in bed for the first 45 minutes.

### Main Study

Recruitment for the main study began in March 2015, and to date 16 participants have been recruited into the study; 8 controls, 4 ideators and 4 attempters. One month follow up interviews began in April 2015.

## **Next Steps**

### Study 1

- Complete remaining 12 month follow-ups for participants; through a combination of post, email and telephone
- Update participants contact details to be contacted again at 24 months for the final follow-up
- Start the 24 month follow-up phase for the study
- Analyze cross-sectional baseline data.

### Study 2

- Continue with participant follow-ups.

### Study 3

- Completion of recruitment to this study and continuing follow ups.

### Study 4

- Completion of recruitment to this study and continuing follow ups.

### Studies 2-4

- Data entry, cleaning and initial analysis of the data.

### Study 5

- Clean up and compute the raw data; data analysis.

### Study 6

- Increase the drive for recruitment.

## **Key Research accomplishments**

### All studies

- All relevant approvals were obtained for carrying out studies 1-6
- We have submitted a review paper on cortisol and suicidality for publication.

### Study 1

- Completion of baseline data collection for Study 1 (3,508 participants recruited from across Scotland)
- Data entry, cleaning and initial exploratory analysis of the study 1 data.
- A total of 97% agreeing to be re-contacted, providing a combination of address, email and telephone number
- Developing online and postal questionnaires to make the follow-up user friendly
- Development of postcard to remind participants about taking part in the study

### Study 2

- All 500 participants recruited.

### Studies 3 and 4

- Participant recruitment is progressing well.

### Studies 5 and 6

- Baseline recruitment complete for Study 5.
- Recruitment for Study 6 is ongoing.

## Reportable Outcomes

There are no further outcomes to report for the other studies at this point.

## Conclusion

The STEPPS project is now into its third year and the studies are progressing well. Recruitment to three of the studies is now complete and the other studies are progressing well. We are well into the follow up phase for all active studies. This phase has presented some challenges for the studies 1 and 2. We have used our experiences effectively and have adapted our procedures for future follow-ups and those in the other studies.

Our program of research is unique in that it looks at a combination of psychological factors that have never been looked at together, particularly across a number of different populations – and will have considerable implications for suicide risk in the military. we are confident that the findings from this research will advance our understanding of the basic psychological processes associated with suicidal ideation and behavior.



## References

- Beck, A.T. et al. (1974). The measurement of pessimism: the hopelessness scale. *Journal of Consulting and Clinical Psychology*, 42, 861-865.
- Beck, A.T., & Steer, R.A. (1993). *Manual for the Beck Scale for Suicide Ideation*. San Antonio, TX: Psychological Corporation.
- Beck, A. T. et al. (1996). *Manual for the BDI-II*. San Antonio, TX: Psychological Corporation.
- Bender, T. W., Gordon, K. H., & Joiner, T. E. (2007). *Impulsivity and suicidality: A test of the mediating role of painful experiences*. Unpublished manuscript. University of FloridaBrenner, L.A.
- Bernstein, D. P., Stein, J. A., Newcomb, M. D., Walker, E., Pogge, D., Ahluvalia, T., Desmond, D. (2003). Development and validation of a brief screening version of the Childhood Trauma Questionnaire. *Child abuse & neglect*, 27(2), 169-190.
- Cohen, S., Kamarck, T., & Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior*, 24, 386–396.
- Campbell-Sills, L. & Stein, M.B. (2007) Psychometric Analysis and Refinement of the Connor-Davidson Resilience Scale (CD-RISC): Validation of a 10-item Measure of Resilience *Journal of Traumatic Stress* 20 (6) 1019-1028.
- Dickerson, S. S., & Kemeny, M. E. (2004). Acute stressors and cortisol responses: a theoretical integration and synthesis of laboratory research. *Psychol Bull*, 130, 355-391.
- Ewing, J.A. (1984) Detecting alcoholism: The CAGE questionnaire. *JAMA: Journal of the American Medical Association*; 252:1905-1907.

Gilbert, P., & Allan, S. (1998). The role of defeat and entrapment (arrested flight) in depression: an exploration of an evolutionary view. *Psychol Med*, 28(3), 585-598.

Godin, G. (2011). The Godin-Shephard Leisure-Time Physical Activity Questionnaire. *Health and Fitness Journal of Canada*, 4, 18-22.

Gratz, K., Hepworth, C., Tull, M., Paulson, A., Clarke, S., Remington, B., & Lejuez, C. (2011). An experimental investigation of emotional willingness and physical pain tolerance in deliberate self-harm: the moderating role of interpersonal distress. *Comprehensive Psychiatry*, 52(1), 63-74.

Hewitt, P. L., & Flett, G. L. (1991). Perfectionism in the self and social contexts: conceptualization, assessment, and association with psychopathology. *Journal of Personality and Social Psychology*, 60, 456-470.

Joiner, T. (2005). *Why People Die by Suicide*. Cambridge: Harvard University Press.

Johnson, J., Gooding, P. & Tarrier, N. (2008). An investigation of aspects of the Cry of Pain model of suicide risk: The role of defeat in impairing memory. *Behaviour Research and Therapy*, 46, 968-975.

Kirschbaum, C., & Hellhammer, D. H. (1989). Salivary cortisol in psychobiological research: A overview. *Neuropsychobiology*.

Kirschbaum, C., Pirke, K. M., & Hellhammer, D. H. (1993). The 'Trier Social Stress Test'—a tool for investigating psychobiological stress responses in a laboratory setting. *Neuropsychobiology*, 28(1-2), 76-81.

Kudielka, B. M., Hellhammer, D. H., & Wust, S. (2009). Why do we respond so differently? Reviewing determinants of human salivary cortisol responses to challenge. [Research Support, Non-U.S. Gov't Review]. *Psychoneuroendocrinology*, 34(1), 2-18. doi: 10.1016/j.psyneuen.2008.10.004

MacDermott, D. (2010). Psychological hardiness and meaning making as protection against sequelae in veterans of the wars in Iraq and Afghanistan. *International Journal of Emergency Mental Health*, 12(3), 199-206.

Madge N, Hewitt A, Hawton K, et al. (2008). Deliberate self-harm within an international community sample of young people: findings from the Child & Adolescent Self-harm in Europe (CASE) Study. *Journal of Child Psychology & Psychiatry*, 49, 667–677.

Meyer, T. J., Miller, M. L., Metzger, R. L., & Borkovec, T. D. (1990). Development and validation of the Penn State worry questionnaire. *Behaviour research and therapy*, 28(6), 487-495.

National Institute for Health and Care Excellence (2004). Self-harm (CG16). London: National Institute for Health and Care Excellence.

Nicholson, S., Jenkins, R., & Meltzer, H. (2009). Suicidal thoughts, suicide attempts and self-harm. In S. McManus, H. Meltzer, T. Brugha, P. Bebbington, & R. Jenkins (Eds.). *Adult Psychiatric Morbidity England, 2007. Results of a Household Survey*.

O'Connor, R. C. (2011). Towards and Integrated Motivation-Volitional Model of Suicidal Behaviour. In R. C. O'Connor, S. Platt & J. Gordon (Eds.), *International Handbook of Suicide Prevention: Research, Policy and Practice* (pp. 181-198). Chichester: WileyBlackwell.

O'Connor, R.C., Fraser, L., Whyte, M.C., MacHale, S., & Masterton, G. (2008). A comparison of specific positive future expectancies and global hopelessness as predictors of suicidal ideation in a prospective study of repeat self-harmers. *Journal of Affective Disorders*, 110, 207-214

O'Connor, R.C., O'Carroll, R.E., Ryan, C., & Smyth, R. (2012). Self-Regulation of Unattainable Goals in Suicide Attempters: A Two Year Prospective Study. *Journal of Affective Disorders*, 142 (1-3), pp. 248-255

O'Connor, D. B., Hendrix, H., Dadd, T., Elliman, T., Willis, T. A., Talbot, D., et al. (2009). Cortisol Awakening Rise in Middle-aged Women in Relation to Psychological stress. *Psychoneuroendocrinology*, 34, 1486-1494.

O'Connor, R.C., Ryan, C., Smyth, R., Masterton, G., & Williams, J.M.G. (2010). The role of psychological factors in predicting short-term outcome following suicidal behaviour. CSO Final Report. Edinburgh.

O'Connor, R.C., Whyte, M.C., Fraser, L., Masterton, G., Miles, J., & MacHale, S. (2007). Predicting short-term Outcome in Well-being Following Suicidal Behaviour: The Conjoint Effects of Social Perfectionism and Positive Future Thinking. *Behaviour Research and Therapy*, 45, 1543-1555.

Patton, J. H., Stanford, M. S. and Barratt, E. S. (1995). Factor structure of the Barratt impulsiveness scale. *Journal of Clinical Psychology*, 51, 768-774.

Pegg, E. J., Deakin, F. J. W., Anderson, I. M., & Elliott, R. (2006). Ruminators show enhanced recognition for items from a failed task. *Journal of Psychopharmacology*, 20 (Suppl.), A58 cited in Johnson, J., Gooding, P. & Tarrier, N. (2008). An investigation of aspects of the Cry of Pain model of suicide risk: The role of defeat in impairing memory. *Behaviour Research and Therapy*, 46, 968-975.

Pilowsky, I. (1967). Dimensions of hypochondriasis. *The British Journal of Psychiatry*, 113(494), 89-93.

Roe, L., Strong, C., Whitesode, C., Neil, A., & Mant, D. (1994). Dietary intervention in primary care: Validity of the DINE Method for diet assessment. *Family Practice*, 11, 375-381.

Scheier, M. F., Carver, C. S., & Bridges, M. W. (1994). Distinguishing optimism from neuroticism (and trait anxiety, self-mastery, and self-esteem): A re-evaluation of the Life Orientation Test. *Journal of Personality and Social Psychology*, 67, 1063-1078.

Smeets, T., Cornelisse, S., Quaedflieg, C. W. E. M., Meyer, T., Jellic, M., & Merckelbach, H. (2012). Introducing the Maastricht Acute Stress Test (MAST): A quick and non-invasive approach to elicit robust autonomic and glucocorticoid stress responses. *Psychoneuroendocrinology*.

Tennant, R., Hiller, L., Fishwick, R., Platt, S., Joseph, S., Weich, S., et al. (2007). The Warwick-Edinburgh mental well-being scale (WEMWBS): Development and UK validation. *Health Qual Life Outcomes*, 27, 63.

Vaglio, J., Conard, M., Poston, W.S., O'Keefe, J., Haddock, C.K., House, J., & Spertus, J.A. (2004). Testing the performance of the ENRICH Social Support Instrument in cardiac patients. *Health & Quality of Life Outcomes*, 2, 24.

Van Orden, K. A., (2009). Construct validity of the Interpersonal Needs Questionnaire. Unpublished Doctoral Dissertation, Florida State University.

Walker, S., O'Connor, D.B., Hendrickx, H., Talbot, D., Schaefer, A. (2011). The cortisol awakening response: Associations with trait anxiety and stress reactivity. *Personality & Individual Differences*, 51, 123-127.

Walker, S., O'Connor, D. B., Schaefer, A., Talbot, D., & Hendrickx, H. (2011). The cortisol awakening response: Associations with trait anxiety and stress reactivity. *Personality and Individual Differences*, 51(2), 123-127. doi: 10.1016/j.paid.2011.03.026

Wrosch, C., Scheier, M.F., Miller, G.E., Schulz, R., & Carver, C.S. (2003). Adaptive self-regulation of unattainable goals: Goal disengagement, goal reengagement and subjective well-being. *Personality and Social Psychology Bulletin*, 33, 251-265.

Zoccola, P. M., Dickerson, S. S., & Zaldivar, F. P. (2008). Rumination and cortisol responses to laboratory stressors. *Psychosom Med*, 70(6), 661-667. doi: 10.1097/PSY.0b013e31817bbc77